

Serial No. 10/750,996
Docket No. SHE0065.00

REMARKS

I. Introductory Comments

In the Office Action under reply, the Examiner has maintained the previous requirement for restriction issued in the Office communication of September 28, 2006. In addition, the Examiner rejected claims 1-37 under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 01/62827.

II. Status of the Claims

Claims 1-65 were previously pending. No amendments to the claims have been made and no claims have been canceled or added. The Examiner has withdrawn from consideration claims 38-65. As a consequence, claims 1-37 remain under consideration.

III. The Restriction Requirement

Applicants reserve their right to petition the Commissioner to review the requirement for restriction, deferring the filing of such petition until after final action on or allowance of the claims, but not later than appeal. See 37 C.F.R. §1.144.

IV. The Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-37 under 35 U.S.C. §103(a) as allegedly being obvious over WO 01/62827.

The rejection is respectfully traversed in view of the following remarks.

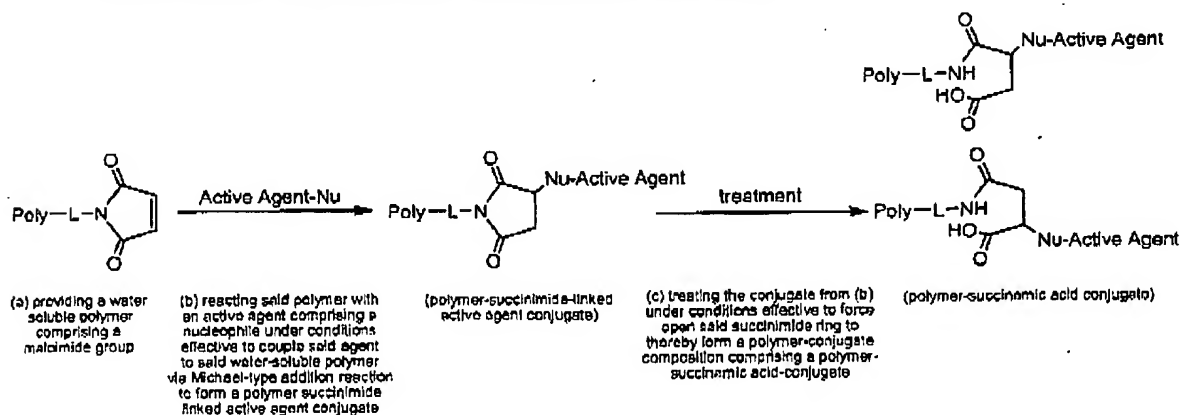
To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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The presently claimed method (claims 1-37) solves (among other things) a problem Applicants' discovered with water-soluble polymers comprising a maleimide group: a tendency for a cyclo group -- a "ring" -- to "open" following coupling to a nucleophile to form a conjugate. When these "ring-opening" events occur within a composition of conjugates, the result is a mixture of "ring-opened" and "ring-closed" conjugates. When the conjugate is a pharmaceutical, for example, such uncontrolled "ring-opening" events are problematic since long-term drug stability and drug consistency are highly desirable features. See Applicants' specification at page 16, lines 4-9.

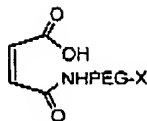
The presently claimed method addresses this problem by "forcing the ring to open." Thus, the claimed method requires: (a) providing a water-soluble polymer comprising a maleimide group; (b) reacting said polymer with an active agent comprising a nucleophile under conditions effective to couple said agent to said water-soluble polymer via Michael-type addition reaction to form a polymer-succinimide-linked active agent conjugate and, (c) treating the conjugate form (b) under conditions effective to force open said succinimide ring to thereby form a polymer-conjugate composition comprising a polymer-succinamic acid-conjugate.

Schematically, these steps can be represented as follows:



As indicated by the Examiner, WO 01/62827 does generally disclose water-soluble polymers comprising a maleimide group, and does generally disclose conjugation with these polymers. The only "ring open" form explicitly disclosed in WO 01/62827 appears on page 13 (twice) and in claim 19, and has the following structure:

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In contrast to Applicants' claimed approach which specifically requires conditions effective to force open the ring to thereby form a polymer-conjugate composition comprising a polymer-succinamic acid-conjugate, WO 01/62827 teaches closing the ring following reaction of a maleic anhydride with "X-PEG-NH₂". Further, WO 01/62827 lacks any recognition of the problem of ring opening, much less teaching or suggesting the claimed feature of intentionally carrying out the treatment step to force open the ring.

Consequently, as WO 01/62827 does not teach or suggest all the claim elements, the third prong of *prima facie* obviousness fails to be satisfied. As a result, the obviousness rejection of claims 1-37 under 35 U.S.C. §103(a) is unsustainable. For at least the reasons provided above, reconsideration and withdrawal of the rejection are respectfully requested.

V. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
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